ATTACHMENT J.4.100

QUALITY ASSURANCE PROGRAM

RM-0012

CONTROL NO. 25K-0130

REQUIREMENTS MANUAL
DOCUMENT NO. RM-0012
REVISION NO. 4

QUALITY ASSURANCE PROGRAM

RM-0012

Effective Date: 11/30/97

AUTHORIZED BY: B D Varchol 11/20/97

Brinley D. Varchol, Quality Assurance FAM **Date**

FERNALD ENVIRONMENTAL MANAGEMENT PROJECT

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RECORD OF ISSUE/REVISIONS

DATE	REV. NO	DESCRIPTION AND AUTHORITY
04-30-92	0	Procedure required for Quality Assurance Program Description, initiated by M.A. Malone per Request No. S92-099. Replaces PL-3014, *Quality Assurance Program Plan*. The content and format were revised to meet requirements of DOE Order 5700.6C. Also, content was revised to incorporate findings under Commitment Number DW:92: 0176.
07-03-92	1	Document revised to resolve comments from DOE per Request No. S92-218, initiated by Jim Turner.
04-30-93	2	Document revised to incorporate organizational changes effected upon change of contracting organization from WEMCO to FERMCO. Revisions also incorporate comments from DOE-EM organizations. Issued for internal review prior to formal revisions. Initiated by Jim Turner.
11-30-94	3	Document revised to incorporate organizational changes; 10 CFR 830.120, Quality Assurance requirements; and review comments. Issued for internal review prior to formal revisions. Initiated by David Ponke. The effective date for the *QAP* is 11/30/94. This date allows for distribution and training for the revised *QAP*.
11-30-97	4	Revision incorporates change notices, editorial & administrative corrections, and organizational updates. This revision does not reflect any minor or major revisions to RM-0012. Includes change notices IC96-16 dated 3/15/96, SC96-007 dated 1/20/96, and SC95-006 dated 1/20/95.

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APPENDICES (Continued)

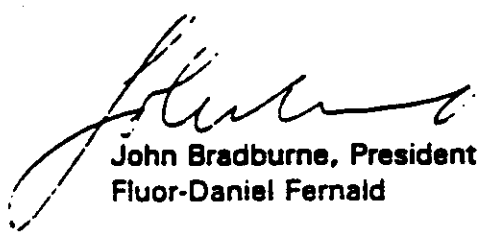
STATEMENT OF QUALITY ASSURANCE AUTHORITY

Fluor-Daniel Fernald (FDF) provides a number of deliverables to the DOE, regulatory agencies and the public. FDF is committed to continuously improve the quality of our products and services. We must do the right thing right, the first time, safely, at least cost, and on time.

The *Quality Assurance Program (QAP)* lescribes the policies and practices which constitute the FDF Quality Assurance I rogram. This program, along with associated policies and procedures, establishes a system for achieving or exceeding the required quality levels for activities associated with the Fernald Environmental Management Project (FEMP). Where and to the extent that activities must be controlled and performed in specific manners or steps, procedures and work instructions will be used with a level of specificity and detail appropriate to the importance or hazard of the activity. Personnel will be trained to these procedures and instructions and expected to follow them exactly. In the event that personnel believe that procedural compliance is unwise or unsafe, they will stop work at a position of process safety and stability and resolve the concerns with appropriate supervision. Procedural changes will then be made as appropriate to continue work.

I retain the responsibility for the overall FDF Quality Assurance Program. The authority for establishing, administering, and evaluating the effectiveness of the Quality Assurance Program is delegated to the Quality Assurance Program Coach. All levels of FDF management are responsible for contributing to the achievement of quality; and for taking a leadership role in ensuring that quality assurance requirements are factored into their work activities, understood by all personnel, continually assessed, and fully implemented. Each person is responsible for compliance with the requirements of quality assurance programs as they apply to their work assignments.

FDF will work towards a "no-fault" attitude to encourage all personnel to identify nonconforming items and processes, and suggest improvements. Every FDF employee must fully support implementation of quality assurance programs and become involved in and support a process of systematic and continuous performance improvement. These efforts are essential to sustain quality and improvement of environmental remediation.



John Bradburne, President
Fluor-Daniel Fernald

INTRODUCTION

1.0 Background

The Department of Energy (DOE) facility at Fernald, Ohio was built in the early 1950s by the U.S. Atomic Energy Commission to process uranium ore concentrates into high-purity uranium-metal products. National Lead of Ohio was the operations and management (O&M) contractor from 1953 to 1986. In 1986, Westinghouse Environmental Management Company of Ohio (WEMCO) (formerly Westinghouse Materials Company of Ohio) assumed this operations and management contract. In 1989, Westinghouse and DOE suspended uranium production operations at Fernald and placed a new focus on environmental restoration for the Fernald site.

In 1991, DOE permanently terminated production operations, reorganized the Fernald site to reflect its environmental restoration mission, and changed the name of the site to the Fernald Environmental Management Project (FEMP). On December 1, 1992, the Fernald Environmental Restoration Management Corporation, now known as Fluor-Daniel Fernald (FDF), assumed responsibility for the FEMP under a new contract structure called an Environmental Restoration Management Contract (ERMC) which was changed to a Performance Based Contract (PBC) in July 1994. In contrast to the previous O&M contracts, the PBC is responsible for the management of all work to perform the environmental remediation of the FEMP within applicable laws, regulations, DOE Orders and commitments.

2.0 FDF Mission Statement

Together, DOE and Fluor Daniel Fernald are committed to safely restoring the Fernald site to an end state which serves the communities' needs, and we will do this within a decade.

An integral part of successfully pursuing this mission is to ensure that the required level of quality in all site activities is achieved, while also taking the necessary measures to ensure the health and safety of site personnel and the public, and safeguarding the environment. The success of the FEMP depends on the required level of quality being achieved in every functional area including: design and analysis, procurement, fabrication, installation, surveying, construction, testing, handling, storing, shipping, operating, maintenance, repair, modification, decontamination, decommissioning, sample collection and analysis, monitoring, measurement, data analysis, inspection, management assessments, independent assessments, training, and documentation.

3.0 Program Standard

The *QAP* uses 10 CFR Part 830.120 for the basic requirements and uses other requirements as stated in the following paragraphs to enhance the QA Program and tailors it to meet the needs of the site. FDF's QA Program also incorporates appropriate requirements from DOE's *QA Rule Implementation Guide*, G-830.120 - Rev. 0 (04/15/94). Statements from this Guide have been identified as either requirements or recommendations (move towards excellence) as documented in both the *Quality Assurance Program* (RM-0012) and the *QA Rule Implementation Plan QARIP* (PL-3029). 10 CFR Part 830.120 is intended to supersede the existing requirements in DOE Order 5700.6C, *Quality Assurance*, for nuclear facilities. The basic requirements of DOE Order 5700.6C and 10 CFR Part 830.120 are identical. Approved management programs based on DOE Order 5700.6C will meet the requirements of 10 CFR Part 830.120.

10 CFR Part 830.120 (QA Rule) requires the preparation of an implementation plan which describes the schedules, milestones, and activities necessary to implement the regulation. The purpose of FDF's *QA Rule Implementation Plan (QARIP)*, PL-3029, is to provide detailed information necessary for FDF to implement (through the *Quality Assurance Program (QAP)*) the requirements of 10 CFR Part 830.120.

Despite broad application of the QA Program at the FEMP, FDF's commitment to implement the QA Rule is confined to two activities - Safe Shutdown Operations, and Material Storage and Handling - conducted in existing facilities rated as Nuclear Hazard Category (HC) 1, 2, or 3. FDF also commits to implement the QA Rule in future activities which may be rated HC1, 2, or 3 in an approved Safety Analysis Report (SAR).

FDF's *Quality Assurance Program (QAP)* is based on the appropriate criteria specified in *10 CFR Part 830.120 Quality Assurance Requirements*

Standards and requirements are identified in the Standards/Requirements Identification Document (S/RID) in RM-0016, *Management Plan*. The successful application of the management system should embrace the philosophy described in DOE/HR-0066. The principles described in DOE/HR-0066 are applied in practice through the application of the criteria of 10 CFR Part 830.120.

4.0 Scope

This *QAP* establishes the QA requirements for FDF and all other contractor and subcontractor organizations performing work at the FEMP. The *QAP* identifies and describes the integral elements of the QA activities that apply to the broad spectrum of work performed by FDF and its contractors and subcontractors for all activities associated with the FEMP.

Major work activities associated with the FEMP are: remedial investigation, feasibility study, removal site evaluations, removal actions, remedial design, remedial actions, Resource Conservation and Recovery Act (RCRA) activities, construction, waste management, safe shutdown, program management and support activities, and landlord activities.

Although it is not necessary for each organization to develop a separate QA Program covering their operation, special QA Program Plans may be developed for programs or projects which require additional control or special emphasis not covered in the *QAP*.

5.0 Description of Program

FDF policy is to establish and implement a QA Program to ensure that risks and environmental impacts are minimized and that safety, reliability, and performance are maximized through the application of effective management systems commensurate with the risks posed by the facility and its work. The QA Program also incorporates requirements for effective planning, implementation, and assessment of environmental sampling and analysis activities.

The *QAP* is organized into three functional categories:

MANAGEMENT	· CRITERION 1 - PROGRAM · CRITERION 2 - PERSONNEL TRAINING AND QUALIFICATION · CRITERION 3 - QUALITY IMPROVEMENT · CRITERION 4 - DOCUMENTS AND RECORDS
PERFORMANCE	· CRITERION 5 - WORK PROCESSES · CRITERION 6 - DESIGN · CRITERION 7 - PROCUREMENT · CRITERION 8 - INSPECTION AND ACCEPTANCE TESTING
ASSESSMENT	· CRITERION 9 - MANAGEMENT ASSESSMENT · CRITERION 10 - INDEPENDENT ASSESSMENT

Within the three functional categories are the QA criteria that provide the basic requirements of a QA Program. Each criterion also identifies responsibilities and outlines the procedural approach that will be followed.

6.0 Program Implementation

A. Graded Approach

The scope and depth of the management system's application of requirements to a specific activity shall be determined by the use of a grading process. The grading process provides the flexibility to design controls that best suit the facility or activity. The graded approach process shall determine the appropriate level of effort necessary to attain and document the requirements established through the consideration of prescribed factors.

This process is based on prescribed facility-specific or activity-specific factors such as the:

- level of risk;
- age, status, and condition of a facility or process;
- history of problems at a site or facility;
- adequacy of existing safety documentation; and
- complexity of products or services involved.

A graded approach and the establishment of Quality Levels are used to determine the appropriate level of effort necessary to implement the requirements of 10 CFR 830.120.

A graded approach as specified in Appendix D - *Graded Approach for Quality Levels*, shall be used to ensure that the resources applied are commensurate with the importance of the result to the achievement of site goals.

B. Implementing Documents

Implementation of the QA Program requires the use of implementing documents which satisfy the provisions of this *QAP*.

RM-0016, *Management Plan* - FDF Policies and Requirements Manual, charters all Functional Area Managers to develop plans and procedures to the requirements of their functional areas.

The *Site Document Index* is updated regularly by FDF and identifies the latest implementing site procedures and revisions. Key site documents which implement QA requirements are listed in Appendix E.

The requirements of QAMS-005/80 and DOE Order 5400.1 apply to all environmental monitoring and measurement efforts mandated by the EPA. The *Federal Facilities Compliance Agreement* and the *Amended Consent Agreement* require that an approved *Quality Assurance Project Plan* (*QAPjP*) be established in accordance with EPA requirements for QA Plans to address data generation activities.

FD-1000, the *Sitewide CERCLA Quality Assurance Project Plan* (*SCQ*), as the principal *QAPjP* for the FEMP, has been developed to cover the EPA QAMS requirements for environmental sampling and analysis to support ultimate remediation of the site. The *SCQ* describes the QC procedures to be followed by DOE and its contractors during the course of remediation of the FEMP. The *SCQ* also describes the QC acceptance criteria used to determine the precision, accuracy, representativeness, comparability, and completeness of environmental measurements. Basic requirements for sampling, sample handling and storage, chain-of-custody records, and laboratory and field analysis are specified in the sections and appendices of the *SCQ*.

C. Should and Shall Statements Usage

The usage of should and shall statements as used in the *QAP* are defined as follows:

- Shall statements are mandatory requirements.

- Should statements affect culture and movements toward excellence. They are not requirements for enforcement. Personnel should strive to attain goals to support site strategic planning.

FUNCTIONAL CATEGORY A: MANAGEMENT

The Management Category contains the program elements that define the framework for the management systems supporting the QA Program that:

- Establishes the responsibility and authority of the functional units of FDF relative to assuring quality of processes and products involved in all activities for the FEMP.
- Describes the role of the QA Organization in establishing and maintaining the QA Program.
- Defines required quality levels for work, outlines organizational responsibilities, provides for training of personnel, and describes the interfacing between organizations to ensure that the varied expertise of the organization is utilized.
- Establishes a system for the prevention, early detection, correction, and reporting of deficiencies, including any breakdown in the management systems, to ensure the quality and improvement of removal, remediation, and remediation support.
- Describes the document control system and the system for the compilation of records which document FDF management of the QA program.

The Management Category is composed of the following criteria:

- Criterion 1 - Program
- Criterion 2 - Personnel Training and Qualification
- Criterion 3 - Quality Improvement
- Criterion 4 - Documents and Records

1.0 CRITERION 1 - PROGRAM

1.1 SCOPE

This criterion describes the requirements and responsibilities for an organization to develop and maintain an effective management system. The management system shall include the methods of managing, performing, and assessing the adequacy of work, including work assigned to parties outside the organization.

The management system shall focus on accomplishing the mission as outlined in the organization's *Management Plan - FDF Policies and Requirements Manual*, RM-0016. The management system applies to every component and employee of the organization, and includes the organizational structure, functional responsibilities, level of authority; and interfaces.

1.2 REQUIREMENTS

1.2.1 FDF shall develop, implement and maintain a written *Quality Assurance Program (QAP)* and submit it to the Lead Program Secretarial Officer (PSO) for approval. FDF subcontractors shall submit their Quality Assurance Programs (where QA programs are required) to FDF Quality Assurance for review and approval.

1.2.2 The *QAP*:

- Describes the organizational structure (Appendix A - FDF Organization Chart), functional responsibilities (Appendix B FDF Organizations and Functions), levels of authority, and interfaces for those managing, performing, and assessing the adequacy of work.

- Describes the onsite and offsite organizational elements, including interfaces for roles and responsibilities of FDF and DOE Fernald Environmental Management Project (DOE-FEMP) in the review of contractor QA Plans.

- Establishes criteria for developing individual QA Plans or combining similar work under a single QA Plan when appropriate.

1.2.3 Organizations conducting environmental sampling and analysis shall comply with quality assurance and quality control requirements specified in FD-1000, *Sitewide CERCLA Quality Assurance Project Plan (SCQ)*, as approved by the DOE and the EPA, as well as with this *QAP*.

Geotechnical analysis and measurements conducted for treatability studies and engineering design studies for environmental decisions

shall comply with the applicable sections of the *SCQ* as stated above.

1.2.4 The applicable requirements of 10 CFR Part 830.120, *Quality Assurance Requirements* of this *QAP* shall be applied to suppliers and subcontractors who perform work under the prime cognizance of FDF or work that affects the responsibility of FDF.

1.2.5 Senior leadership shall develop and issue a written QA Policy Statement which commits FDF to implement a formal QA Program.

1.2.6 Senior leadership shall retain and exercise the responsibility for the scope and implementation of an effective QA Program.

1.2.7 Line leadership shall be responsible for the achievement of quality.

1.2.8 Individuals shall be responsible for the quality of their work.

1.2.9 The QA Program should promote effective and efficient achievement of performance objectives.

1.2.10 The QA Program shall be binding on all personnel, including those having responsibility for planning and scheduling. FDF leadership shall take the necessary actions to ensure that the QA Program is understood and implemented.

1.2.11 A common vocabulary consistent with and representative of work being performed shall be adopted. (Appendix C)

1.2.12 Key terminology shall be defined. (Appendix C)

1.2.13 The quality of items and processes shall be ensured to an extent consistent with their potential impact on the safe and reliable operation of the FEMP. A graded approach, as specified in Appendix D - *Graded Approach for Quality Levels*, shall be used to ensure that the resources applied are commensurate with the importance of the result to the achievement of site goals.

1.2.14 Work assigned to parties outside FDF (contractors, subcontractors, suppliers, etc.) shall be identified. Management controls shall be established, responsibilities assigned, and lines of communication identified.

1.2.15 Organizations should ensure that initial estimates used in planning are based on valid data and assumptions relating to personnel, material/service costs, availabilities, and productivity.

1.2.16 Readiness reviews shall be performed prior to initiation of major work activities identified to require readiness review. Readiness reviews shall be performed to verify at least the following characteristics:

Work prerequisites have been satisfied, including regulatory compliance issues.

- Detailed technical and QA procedures have been reviewed for adequacy and appropriateness.
- Training programs are in place.
- Personnel have been suitably trained and qualified.
- Proper equipment, material, and resources are available.

1.2.17 A readiness review using a graded approach shall be performed in accordance with Paragraph 1.2.16 prior to restarting work affected by a stop work order.

1.2.18 FDF shall assign the responsibility and authority to stop unsatisfactory work and control further processing, delivery, installation, or use of nonconforming items such that planning and schedule considerations do not override safety, quality, or environmental considerations.

1.3 RESPONSIBILITIES

1.3.1 President of FDF shall:

- Retain the authority and responsibility for the overall QA Program of FDF. This authority extends to the review and approval of this *QAP*.
- Establish the QA Policy for FDF.

1.3.2 The Quality Assurance Organization shall:

- Provide FDF with systems for a quality assurance program that provide assurance that all FEMP organizations, projects, systems, operations, activities, and processes are managed and operated to achieve intended results and that items and services supplied or procured meet the intended or required standards.

- Develop the QA Program, with input from all senior leadership, monitor its implementation and effectiveness, and coordinate the FDF Organizations' QA functions.

- Review and approve other FDF contractor Quality Assurance Program Plans/Descriptions (where QA programs are required).

- Issue a Stop Work Order, as authorized by the Quality Assurance Program Coach, for a significant condition adverse to quality in which continued work could prevent repair or in which there is a major programmatic breakdown that impacts a major portion of the work being performed.

1.3.3 Leadership of FDF Organizations shall:

- Retain the primary responsibility and are accountable for the scope and implementation of the management system. However, every individual in the organization is responsible for achieving quality in his or her activities.

- Promote effective achievement of performance objectives through the:

  - establishment of task assignments;

  - identification of lines of communication; and

  - determination and provision of the necessary resources and environment to accomplish the required activities.

- Ensure the achievement of quality in the products, processes, services, and work activities assigned to their organizations.

- Conduct their organization's operations in compliance with the applicable requirements of this *QAP*.

- Perform evaluation of structures, equipment, systems, components, and processes relative to their importance to safety, reliability, and other quality functions.

- Provide their personnel with the necessary orientation and training to ensure compliance with existing, new, or revised implementing procedures.

- Ensure, for all assigned work, that the management controls shall include the establishment of responsibilities and the identification of lines of communication.

- Ensure, that all personnel understand and implement the management system.

1.4 IMPLEMENTATION

1.4.1 Graded Approach

The scope and depth of the management system's application of requirements to a specific activity shall be determined by the use of a grading process. The grading process provides the flexibility to design controls that best suit the facility or activity. The graded approach process shall determine the appropriate level of effort necessary to attain and document the requirements established through the consideration of prescribed factors.

This process is based on prescribed facility-specific or activity-specific factors such as the:

- level of risk;
- age, status, and condition of a facility or process;
- history of problems at a site or facility;
- adequacy of existing safety documentation; and
- complexity of products or services involved.

A graded approach and the establishment of Quality Levels are used to determine the appropriate level of effort necessary to implement the requirements of 10 CFR 830.120.

A graded approach as specified in Appendix D - *Graded Approach for Quality Levels*, shall be used to ensure that the resources applied are commensurate with the importance of the result to the achievement of site goals.

1.4.2 Implementing Documents

The process for developing and using plans and procedures and their implementation is outlined in RM-0016, *Management Plan - FDF Policies and Requirements Manual*. RM-0016 charters all Functional Area Managers to develop plans and procedures to the requirements of their functional areas.

The *Site Document Index* is updated monthly by the Program Support Organization and identifies the latest implementing site procedures and revisions. A current listing of key site documents which implement QA requirements are included in Appendix E.

This list is officially maintained and controlled in RM-0016, *Management Plan - FDF Policies and Requirements Manual.*

2.0 CRITERION 2 - PERSONNEL TRAINING AND QUALIFICATION

2.1 SCOPE

This criterion describes the FDF requirements for personnel to be trained and qualified to ensure they are capable of performing their assigned work. Personnel shall be provided continued training to ensure that job proficiency is maintained.

2.2 REQUIREMENTS

2.2.1 A formal training program for Resource Conservation and Recovery Act (RCRA) hazardous waste personnel shall be developed for the Fernald Environmental Management Project (FEMP) as required by Ohio Administrative Code (OAC) 3745-50-44(A)(12), OAC 3745-54-16, Title 40 Code of Federal Regulation (CFR) 270.14 (b) (12) and 40 CFR 264.16.

The training program shall also meet the training requirements for RCRA permitted treatment, storage and disposal facilities prescribed in the Occupational Safety and Health Act (OSHA) regulations in 29 CFR 1910.120.

2.2.2 All personnel shall be capable of performing their assigned tasks. Training shall prepare the employee to perform the job, as well as, maintain and promote progressive improvement and employee satisfaction. Qualification requirements (experience, education, and training) shall be documented for each position as required.

2.2.3 Training shall provide the worker with an understanding of the processes and tools required. Using the graded approach, it shall cover the extent and sources of variability in those processes and tools, the degree to which the worker does and does not have control over that variability, and an understanding of the fundamentals of the work.

2.2.4 Training shall emphasize requirements for performance of work and provide understanding of why quality requirements exist. The training shall focus attention on doing the right things the first time and address potential consequences of improper work.

2.2.5 The training shall be presented by trained and qualified instructors. They may be training providers or qualified members of the organization requiring the training. Instructors shall possess technical knowledge, experience, course development and instructional skills.

2.2.6 Training plans shall address and stimulate job performance. They are to provide for progressive improvement and shall not be limited to initial qualification for job proficiency. Training plans for management personnel should include professional, managerial, communication, and interpersonal skills.

2.2.7 Personnel performing work that requires special skills/abilities such as welding or legally required training shall be qualified (and certified, if required) prior to performing that work. The certification program is to include demonstrated proficiency.

2.2.8 Training programs shall be periodically reviewed to determine program and instruction effectiveness, and shall be upgraded when required.

2.2.9 Completion of training shall be documented in accordance with established procedures, and those documents shall be filed and maintained in Training Records.

2.3 RESPONSIBILITIES

2.3.1 The Oversight and Program Integration organization shall:

- Develop programs and procedures pertaining to training.
- Establish site indoctrination and training programs and procedures.
- Ensure that FDF technical training and professional development training programs are in compliance with DOE and other regulatory requirements.
- Ensure the effectiveness of technical training.

2.3.2 Program Support shall:

- Maintain and administer the Training Records System.
- Maintain a file on the training required for each position description based on input from management.

2.3.3 FDF Leadership shall:

- Identify and document those work functions requiring special skills and implement training procedures to ensure the adequacy of personnel proficiency for work to be performed; identify minimum education and experience requirements to perform the work; and identify general training topics.

- Identify the operations under their responsibility which must comply with mandatory training requirements and which need trained, qualified, and certified employees.

- Prepare a training plan for employees, which includes continued training required to maintain job proficiency. This should include understanding of processes and tools used, limitations on the use and operation of the processes and tools, sources of variability, and the limitation to the degree of control over those sources of variability.

- Ensure that the required indoctrination, training, and qualification for a specified task is completed prior to employees performing the task.

- Ensure that personnel including subcontractors and temporaries performing work for the organization are suitably qualified to accomplish their assigned tasks. Personnel may be qualified by:

  - considering previous experience, education, and training;

  - demonstrating and testing to verify previously acquired skills; or

  - completing a training or qualification program.

2.3.4 Human Resources Department of the Program Support Organization shall:

- Develop and maintain position descriptions and associated individual experience and educational records.

- Perform verification of personnel qualification, education, and experience.

- Administer the new employee indoctrination program.

- Maintain a file containing the written job title and written job description for each position at the FEMP.

2.3.5 The Human Resources Department and Professional Staffing Section of the Program Support Organization shall:

- Administer professional development training.

- Administer professional development programs.

- Monitor their effectiveness.

2.3.6 The Quality Assurance Organization shall:

- Certify Level III nondestructive examination personnel in Quality Assurance to American Society of Nondestructive Testing (ASNT) standards.
- Certify Level I & II nondestructive examination personnel by its Level III person(s) to ASNT standards.
- Certify auditing personnel.
- Conduct independent overview of training activities to assure compliance with program requirements.
- Certify Lead Auditors and maintain records of certification.

2.3.7 The FDF personnel shall:

- Attend training as scheduled.
- Refrain from operating equipment or performing work until proper training has been completed.

3.0 CRITERION 3 - QUALITY IMPROVEMENT

3.1 SCOPE

This criterion describes the requirements and responsibilities for establishing and implementing processes to detect, control, correct, and prevent quality problems and to promote quality improvement.

3.2 REQUIREMENTS

3.2.1 The FDF QA Program shall establish and implement processes to detect and prevent quality problems and promote continuous quality improvement. The focus of quality improvement shall be to improve the quality of items and processes.

3.2.2 A trend analysis system shall be developed that identifies trends that adversely impact quality and opportunities to improve the quality of items or processes. This analysis shall consider information from external sources and not be limited to one type, one facility, or one contractor.

3.2.3 A system shall be established where items, activities, and processes that do not meet specified requirements are identified, controlled, and corrected to prevent their inadvertent test, installation, or use.

Items and processes shall be reviewed by qualified and knowledgeable personnel, and a justification for the disposition shall be documented.

Controls shall provide for the identification, documentation, evaluation, segregation where practical, and disposition of deviations and for notification to affected organizations.

3.2.4 The corrective action program shall include the identification of the causes of problems to preclude recurrence.

3.2.5 Item characteristics, process implementation, and other quality-related information shall be reviewed and the data analyzed to identify items and processes needing improvement.

3.2.6 Leadership, at all levels, will work towards and foster a "no-fault" attitude to encourage the identification of nonconforming items and processes. Leadership will also encourage personnel to identify and promote performance improvement.

3.2.7 Reworked and replacement items and processes shall be inspected and tested in accordance with original requirements. Repaired items and processes shall be inspected and tested in accordance with specified alternatives to original requirements.

3.2.8 A process for resolving professional differences of views and opinions shall be established.

3.3 RESPONSIBILITIES

3.3.1 Total Quality Management Organization:

- Develop policy that enhances continuous performance improvement in the quality and productivity of FDF services and products.
- Identify and prioritize key company quality issues.
- Establish teams to resolve key company quality issues and monitor the teams progress.
- Encourage employee involvement and cultural changes to effect the changes that are needed to improve FDF's quality performance.
- Promote activities which recognize employee contributions to continuous performance improvement.

3.3.2 The FDF Employee Advocate shall:

- Provide a communication channel from employees directly through the Employee Advocate to the FDF President and/or appropriate FDF leadership.
- Review inputs for trends and systemic problems which require the attention of the FDF President and/or appropriate FDF leadership.

3.3.3 FDF leadership is responsible for building a culture in which improvement is continuous and an integral part of the organization. FDF leadership shall:

- Increase FDF personnel awareness of the importance of quality.
- Encourage FDF personnel to identify and suggest improvements through the Fernald Employee Suggestion System (FESS).

- Ensure that items that do not conform to specified requirements are controlled to prevent inadvertent installation or use.

- Ensure that any condition adverse to quality detected for items within their cognizance are identified, reported, and processed in accordance with established procedures.

- Determine and specify disposition of the nonconforming condition.

- Focus upon problem prevention and performance improvement, rather than detecting and reacting to problems after they occur.

- Evaluate and measure processes and performance to identify potential problem areas, identify trends in productivity and quality, apply lessons learned, and develop actions that can be taken to improve performance.

3.3.4 The FDF personnel shall identify and report any condition adverse to quality to responsible FDF leadership in accordance with established procedures.

3.3.5 All personnel should know how their process contributes to the strategic goals of the organization.

3.3.6 Quality Assurance Organization shall:

- Develop site policies and procedures which govern the identification, control and disposition of nonconformances and corrective actions.

- Ensure that personnel document (using the nonconformance process for corrective actions) the significant condition adverse to quality, review the record of evaluation and specified corrective action, and verify the completion of corrective action.

- Ensure the control of the issuance, resolution, closure and tracking of nonconformances.

- Ensure that personnel have the authority to tag nonconforming items and ensure segregation to prevent inadvertent test, installation, or use of the items.

3.3.7 The Contracts and Asset Management Organization shall:

- Advise requisitioners and subcontract performance inspectors of contractual quality provisions and procedures.
- Employ the necessary procurement actions to mitigate supplier-caused nonconformances when reported by the requisitioner or performance inspector.
- Establish a Cost Control System.

3.3.8 Oversight & Program Integration Organization shall:

- Provide an overall program planning, scheduling and performance tracking system.
- Establish and implement a central tracking and commitment control system.

4.0 CRITERION 4 - DOCUMENTS AND RECORDS

4.1 SCOPE

This criterion describes the requirements and responsibilities for establishing and implementing a system for the control of documents and the handling, collection, storage, and control of records generated at the FEMP.

4.2 REQUIREMENTS

4.2.1 A system shall be established and implemented to control preparation, review, approval, issuance, use, and revision of documents that establish policies, prescribe work, specify requirements, or establish design. The scope of the document control system shall be defined.

4.2.2 Revisions to controlled documents shall be reviewed and approved by the organization that originally reviewed and approved them. An alternative organization may be designated based on technical competence and capability.

4.2.3 A system shall be established to ensure that controlled documents are distributed to and used by personnel performing work. Timeliness guidelines shall be implemented for distribution of new or revised controlled documents.

4.2.4 Control of superseded and canceled documents shall include measures to ensure that only correct documents are in use. Record copies should be marked "superseded" or "canceled" and kept for a specified retention period. Superseded and canceled controlled documents required for reference must be removed from the field but may be kept in field offices. These documents must be stamped "VOID."

4.2.5 A system shall be established for implementation of processes to ensure that records are specified, prepared, legible, reviewed, approved, and maintained to accurately reflect completed work.

4.2.6 The maintenance of records shall include provisions for retention, protection, preservation, traceability, accountability, and retrievability. Care shall be taken to ensure that the requirements of the National Archives and Records Administration (NARA), applicable standards, and any additional statuary requirements are met.

4.2.7 Evidentiary records shall have appropriate procedures controlling media type, chain of custody, and confidentiality.

4.2.8 Records shall not be erased or obliterated when revised. Instead, a single line shall be drawn through errors or items to be deleted. The person making a revision shall initial and date the revision. Changed records must undergo the same review as original quality assurance records. This includes re-review by persons who have reviewed the record prior to the changes.

4.2.9 For records that require special processing and control, such as computer codes or information on high density media or optical disks, hardware and software required to maintain and access records shall be controlled to ensure records are useable and readily retrievable.

4.2.10 Records containing data used to support CERCLA decision making shall meet the requirements defined in the Sitewide CERCLA Quality Assurance Project Plan. These records shall be contained in the Administrative Record, an official repository for programs and projects aimed at remediation of the FEMP. Contents of the Administrative Record are determined by DOE and are accessible to the public.

4.2.11 Changes in automated data entries shall:

- not obscure the original entry;
- indicate the reason for change;
- be flagged as changed;
- be dated; and
- identify the individual making the change.

4.2.12 Approval for final disposition of government records shall be obtained from the National Archives and Records Administration (NARA).

4.2.13 All records management systems shall have schedules for records retention and disposition in accordance with the requirements of NARA and DOE 1324.2, Records Disposition.

4.3 RESPONSIBILITIES

4.3.1 Records Management Department of the Program Support Organization shall:

- Develop and maintain site policies and procedures to direct the identification and control of records.

- Operate a record storage vault for the storage of quality assurance records.

4.3.2 Program Support Organization shall:

- Establish and implement site document control system and procedures to implement that system.
- Ensure historical copies of superseded site documents are maintained.
- Develop and maintain a system which controls and lists current site documents and their latest revisions.

4.3.3 FDF Leadership shall:

- Implement the QA Program requirements through the use of plans and procedures which satisfy the provisions of this *QAP*. The process for developing and using plans and procedures and their implementation is outlined in RM-0016, *Management Plan - FDF Policies and Requirements Manual.* RM-0016 charters all Functional Area Managers to develop plans and procedures to the requirements of their functional areas.
- Utilize the site document control procedures to establish their organization document control system.
- Obtain the required reviews and approvals for documents to be issued.
- Issue documents as controlled procedures.
- Route site organization documents to other interfacing or impacted organizations for review and ensure that the review and comment resolution process is completed. Organizations outside the site organization cannot be tasked in, nor directly affected by, site organizational documents; that is the sole purview of site-level documents.
- Ensure that historical copies of superseded organization documents are maintained in accordance with FDF procedures for record storage.
- Identify and control records within their area of responsibility.

4.3.4 Holders of Controlled Documents shall:

- Maintain the latest revision of documents until superseded.
- Verify documents against revisions.
- Dispose of superseded documents to avoid inadvertent use in subsequent work activity.

4.3.5 The FDF personnel shall:

- Ensure that correct revisions of documents are used for performing work activities.
- Ensure that records are properly maintained and safeguarded.

4.3.6 Engineering Organization shall establish and implement a system for the control and distribution of design documents. This system shall include a master drawing index for all engineering drawings issued, which indicates the most current revision issued for each drawing.

4.3.7 FEMP Administrative Record Coordinator shall maintain the evidence files for CERCLA decision making as part of the Administrative Record, and maintain files of all other environmental sampling and analysis files which could potentially be used to support future environmental decisions.

4.3.8 Quality Assurance Organization shall:

- Perform surveillances and audits of the document control system(s).
- Assist and guide all FDF organizations in generating, handling, storage, management, and dispositioning of Quality Assurance Records.
- Perform surveillances and audits of the control and storage of QA Records system for the FEMP.

FUNCTIONAL CATEGORY B: PERFORMANCE

The Performance Category provides for controlling activities associated with establishing and maintaining the technical requirements for our work that includes provisions for:

- The design and procurement specifications and requirements for testing.
- The control of approved instructions, procedures, drawings, and other appropriate documents.
- The control of processes used in site restoration, environmentally related measurements, handling wastes, and in the construction and maintenance of facilities.
- Calibration of measuring and test equipment used in these processes to maintain accuracy.
- The receipt of items or items manufactured by FDF are identified and controlled to verify they conform to established requirements.
- Handling, storage, and shipping of materials to protect against loss of containment integrity and physical damage.
- Using approved suppliers of purchased material, equipment, and services which satisfy company requirements.
- Items (i.e., hazardous waste, environmental media, and product) to be monitored, measured, and tested.
- Monitoring and observations of associated processes during construction, operations (including environmental monitoring), and site restoration activities to determine conformance to procedural and technical requirements and to ensure continuous improvement in the quality of all products and services.
- The acceptance status of items subject to inspection and testing is known throughout these operations.

The Performance Category is composed of the following criteria:

- Criterion 5 - Work Processes
- Criterion 6 - Design
- Criterion 7 - Procurement
- Criterion 8 - Inspection and Acceptance Testing

5.0 CRITERION 5 - WORK PROCESSES

5.1 SCOPE

This criterion describes the requirements and responsibilities for the control of processes affecting all work processes. A work process includes all activities involved in performing defined tasks to achieve an objective. Work processes may include activities as planning, scheduling, accounting, project management, design, analysis, fabrication, procurement, construction, installation, testing, operation, modification, maintenance, and decommissioning.

The purpose of work process control is to ensure that standard processes and special processes are accomplished under controlled conditions. These standard processes and special processes include, but are not limited to: waste handling, packaging, certification and shipping; environmental data operations; welding; heat treating; core drilling; or nondestructive testing.

Items shall be identified and controlled to ensure their proper use. Items shall be maintained to prevent their damage, loss, deterioration. Equipment used for process monitoring or data collection shall be calibrated and maintained.

5.2 WORK REQUIREMENTS

5.2.1 Work related instructions, procedures, and other forms of direction shall be developed, verified, validated and approved by technically competent personnel, and shall be provided to employees doing the work.

5.2.2 Work shall be performed to established technical standards and administrative controls. Work shall be planned, authorized and accomplished under controlled conditions using technical standards, instructions, procedures, or other appropriate means of detail commensurate with the complexity and importance of the work.

5.2.3 FDF personnel performing work are responsible for the quality of their work.

5.2.4 FDF leadership shall review work and related information to ensure that the desired quality is being achieved and to identify areas needing improvement.

5.3 IDENTIFICATION AND CONTROL OF ITEMS REQUIREMENTS

5.3.1 A system shall be established for the implementation of processes to identify, control, and maintain items; control consumables and items with limited shelf life; prevent the use of incorrect or defective items; and control samples.

5.3.2 A system for the identification and control of items shall be established to ensure their proper use and traceability. Items shall be maintained to prevent their damage, loss, or deterioration.

5.4 HANDLING, STORING AND SHIPPING REQUIREMENTS

5.4.1 A system shall be implemented for a process to control the handling, storage, shipping, cleaning, and preservation of items to prevent damage, loss, or deterioration. Marking and labeling of items shall be maintained throughout packaging, shipping, handling, and storage.

5.4.2 Requirements for offsite transportation shall be established and implemented. Special protective measures shall be specified and provided when required to maintain acceptable quality.

5.4.3 Low-level waste shipments to the Nevada Test Site shall meet the requirements of NTSWAC, Nevada Test Site Waste Acceptance Criteria.

5.5 CALIBRATION AND MAINTENANCE OF MONITORING AND DATA COLLECTION EQUIPMENT REQUIREMENTS

5.5.1 A system shall be established for the implementation of a process to control the calibration, maintenance, and use of measuring and test equipment used for monitoring and data collection.

5.5.2 Monitoring and data collection equipment shall be of the accuracy and type suitable for the intended use. The types of equipment shall be specified in work documents. Equipment shall have calibration certifications traceable to national standards, where possible. Equipment on which calibration is overdue shall be tagged to prevent use until calibrated.

5.6 WORK RESPONSIBILITIES

5.6.1 Project Controls Organization shall:

- Ensure overall program integration activities are implemented.
- Ensure site planning and scheduling activities are completed.
- Perform project budgeting and analysis activities.
- Establish a directive management system.

5.6.2 FDF Leadership shall:

- Develop budget and schedules.
- Clearly identify authorities, responsibilities, and interfaces, both internal and external, regarding the work process in appropriate work process documents.
- Ensure that activities affecting quality under their cognizance are prescribed and controlled by instructions, procedures, or drawings.
- Ensure that work done by their organizations is performed to appropriate technical standards or administrative controls.
- Establish policies and procedures for all aspects of work control and performance consistent with applicable DOE orders and other regulations.
- Ensure procedures, instructions, and other work control documents include requirements for process controls and formal qualifications. Work-related forms of direction shall include clearly identifiable caution statements when warranted.
- Establish processes to identify, control, and maintain items; control consumables and items with limited shelf life; prevent the use of incorrect or defective items; and control samples.
- Conduct a self-evaluation process to monitor performance for use in self-assessment and continuous improvement activities.

- Ensure that employees are provided the necessary training, resources, and direction to perform their work assignments. This includes familiarity with tools, equipment, and quality requirements.

- Ensure that applicable employees are trained to new conditions if the work process is changed.

5.6.3 FDF Leadership should include personnel performing a process in process improvement activities.

5.6.4 The FDF personnel shall:

- Perform work to approved requirement documents (e.g., plans, procedures, drawings, and specifications).

- Perform work in a sequence consistent with the prerequisite activities.

- Perform work with the proper tools and equipment.

5.6.5 The FDF personnel should set goals for doing the work correctly the first time and contribute to improved work processes.

5.6.6 The Quality Assurance Organization shall:

- Inspect work activities and implementing documents to ensure compliance with specified requirements.

- Provide QA inputs into planning of site project work plans.

- Perform reviews, surveillances, assessments, and audits of work activities and implementing documents to ensure compliance to specified programmatic requirements.

5.7 IDENTIFICATION AND CONTROL OF ITEMS RESPONSIBILITIES

5.7.1 FDF Organizations shall:

- Specify methods and requirements for identifying environmental samples and other items.

- Assign custody authority for environmental samples.

5.7.2 Quality Assurance Organization shall:

- Review work and procurement documents for item identification provisions.

- Verify that identification has been applied to items in accordance with specified requirements.

5.8 HANDLING, STORING AND SHIPPING RESPONSIBILITIES

5.8.1 RDF Organizations shall:

- Ensure procedures are established for controlling the handling, storage, shipment, and disposal of radioactive and hazardous waste material including chain-of-custody, travelers, and other measures necessary to control environmental samples, drums, and other containers of waste.

- Implement chain-of-custody procedures for controlling the handling, storage, shipping, and disposal of environmental samples. These procedures for environmental samples shall be taken from the *SCQ* (as approved by the DOE and EPA).

- Include handling, shipping, and storage requirements in equipment specifications, drawings, and procurement documents, as applicable. Items shall be maintained to prevent their damage, loss, or deterioration.

5.8.2 The Waste Acceptance Organization shall:

- Verify the acceptability of the processes to ensure handling, storage, shipping, cleaning and preservation of items.

- Verify the acceptability, marking, and content of each waste package.

- Certify low-level waste shipments.

- Examine highway transport vehicles used for off-site hazardous waste shipments.

- Review work and procurement documents to assure that provisions for item identification are specified.

5.8.3 The Quality Assurance Organization shall:

- Plan and perform audits and surveillances, including the verification of compliance with sitewide requirements for interim storage of hazardous wastes.

5.9 CALIBRATION AND MAINTENANCE OF MONITORING AND DATA COLLECTION EQUIPMENT RESPONSIBILITIES

5.9.1 FDF Organizations shall:

- Identify devices which require calibration.
- Establish systems to calibrate such devices. Calibration of equipment for environmental sampling shall be in accordance with the *SCQ* (as approved by DOE and EPA).
- Establish a system to control the use of such devices.

6.0 CRITERION 6 - DESIGN

6.1 SCOPE

This criterion describes the requirements and responsibilities for the implementation of a formal design control process. Design work is based on sound engineering/scientific principles and appropriate standards. The requirements of this criterion apply to all organizations that perform design or are responsible for design performed by contractors or subcontractors.

6.2 REQUIREMENTS

6.2.1 A program for the design of items and processes shall be established and implemented using sound engineering/scientific principles and appropriate standards.

A formal design process shall be established which provides control of design inputs, outputs, verification, configuration and design changes, documentation, records, and technical administrative interfaces.

The administrative interface process shall clearly indicate responsibilities for design output document activities including as-built mark-up and updating during project construction/production phases, media use and transmission, document control, and records management.

6.2.2 Design inputs (such as the design bases) are to be correctly translated into design outputs (such as specifications, drawings, procedures, and instructions).

Design outputs are to be suitable for intended use. Aspects critical to the safety or reliability of the designed Systems, Structures, and Components shall be identified during the design phase.

Systems, Structures, and Components important to safety shall be subject to more stringent operational criteria and verification requirements than those not important to safety.

6.2.3 Changes to final designs (including nonconforming items that are dispositioned "use as is" or "repair") are to be subjected to design control measures commensurate with those applied to the original design and approved by the organization that approved the original design or a qualified designate.

Temporary modifications shall receive the same levels of control as the designs of permanent modifications.

6.2.4 Design interface controls (internal and external between participating design organizations and across technical disciplines) for the purpose of developing, reviewing, approving, releasing, distributing, and revising design inputs and outputs are to be defined.

6.2.5 Design records, maintained to provide evidence that the design was properly accomplished, are to include not only the final design output and revisions to the final output, but also the important design steps (calculations, analyses, and computer programs, for example) and the sources of input that support the final output.

6.2.6 The acceptability of design activities and documents, including design inputs, processes, outputs, and changes, are to be verified.

Design verification is a formal documented process to establish that the resulting Systems, Structures, and Components will be fit for the intended use.

Computer programs are to be proven through previous use, or verified through testing or simulation prior to use.

6.2.7 The data collection process for characterizing environmental processes and conditions shall be defined, controlled, verified, and documented.

6.2.8 Design verifications are to be conducted by qualified personnel who are knowledgeable of the design and its intent. These personnel may be from the same organization, but must not be those who performed the original design.

The extent and number of design verifications shall be based on a graded approach and shall depend on the design product's complexity and importance to project success.

6.2.9 Design verification methods are to include, but are not limited to, technical reviews, peer reviews, alternate calculation, and qualification testing.

Separate verification may not be needed for multiple uses of identical or previously proved designs, unless they are intended for different applications or the performance criteria are different.

6.2.10 When a test program is used to verify the acceptability of a specific design feature, the test program is to demonstrate acceptable performance under conditions that simulate the most adverse design conditions that are expected to be encountered.

6.2.11 Design verification and validation work shall be completed and documented before approval and implementation of the design outputs are used by other organizations for design work and before they are used to support other activities such as procurement, fabrication, construction, or experimentation.

When timing cannot be achieved, the unverified portion of the design shall be identified and controlled. In all cases, design verifications shall be completed before relying on the Systems, Structures, and Components to perform its function and before installation becomes irreversible.

6.2.12 Changes to computer software shall be controlled to assess the potential impact of the change on the performance of the software.

6.2.13 As-built drawings and shop drawings shall be maintained after production or construction to show actual configuration.

6.3 RESPONSIBILITIES

6.3.1 The Project Engineering Organization shall:

- Implement a formal design program to ensure that engineered systems are designed using sound engineering/scientific principles. This program is to include provisions to control design inputs, processes, outputs, changes, interfaces, records, and organization interfaces.

  Designs shall provide for appropriate inspection, testing, and maintenance to ensure continuing reliability and safety of the Systems, Structures, and Components. Inspections and tests shall be conducted according to a graded approach.

  The design shall consider the expected use and life expectancy of the Systems, Structures, and Components in order to address appropriate disassembly and disposal requirements.

- Plan, coordinate, and document design of engineered systems used in protecting human health, safety, and the environment.

- Incorporate quality-affecting design requirements in design documents, such as drawings, specifications, and test procedures.

- Coordinate and interface with organizations required to participate in the design process.

- Assign responsibility for determining technical correctness of inputs and translations into design documents.
- Assure the status of each Safe Shutdown program is included in documents.

6.3.2 The Quality Assurance Organization shall:

- Review design documents to ensure that quality attributes are specified and that design control procedures have been followed.
- Provide QA system requirements into design documents.
- Inspect to design specifications.
- Perform surveillances and audits to verify that the design process meets established requirements.

7.0 CRITERION 7 - PROCUREMENT

7.1 SCOPE

This criterion describes the requirements and responsibilities for the preparation, review, and control of procurement documents. It also specifies the requirements and responsibilities for the control of purchased material, equipment, and services.

7.2 REQUIREMENTS

7.2.1 A program shall be established and implemented to ensure that purchased items and services meet established requirements and perform as expected.

The applicable requirements of 10 CFR Part 830.120 Nuclear Safety Management and of this *QAP* shall be applied to suppliers and subcontractors who perform work under the prime cognizance of FDF or work that affects the responsibility of FDF.

7.2.2 Applicable technical and administrative requirements (such as specifications, codes, standards, tests and inspections, and acceptance criteria) shall be invoked for procurement of items and services.

Procurement documents shall include any specifications, standards, and other documents referred to by the design documents. Procurement documents shall clearly state test/inspection requirements and acceptance criteria for purchased items and services.

Critical parameters and requirements such as submittals, product-related documentation, nonconformance requirements, administrative documentation, personnel or materials qualification, tests, inspections, and reviews shall be specified as line items.

7.2.3 Appropriate controls shall be established and implemented for the selection, determination of suitability, evaluation, and receipt of commercial-grade items to ensure that commercial-grade items perform as expected.

7.2.4 Prospective suppliers are to be evaluated to ensure that only qualified suppliers are selected. The prospective suppliers shall be evaluated to verify their capabilities to meet performance and schedule requirements.

Measures for evaluating and selecting suppliers may include:

- a review of the supplier's history for providing identical or similar items or services;
- an assessment of the supplier's capability based on evaluation of its facilities, personnel, and programs; or
- an evaluation of documented qualitative and quantitative information provided by the supplier.

7.2.5 Procurement of laboratory subcontractors for analyzing environmental samples shall be strictly controlled. Only laboratories that have a demonstrated capability to provide the level of data quality required for a program or project shall be contracted.

7.2.6 The qualified suppliers are to be evaluated periodically to confirm their continuing capabilities to provide acceptable products and services. Required supplier monitoring shall be performed during the procurement process to ensure that acceptable items or services and schedule requirements are being met.

Monitoring may include:

- surveillance of work activities;
- inspection of facilities and processes;
- review of plans and progress reports;
- processing of change information; and
- review and disposition of nonconformances.

7.2.7 Purchased items and services are to be accepted using specified methods (such as source verification, receipt inspection, pre-installation and post-installation tests, and certificates of conformance, or a combination of these methods).

7.2.8 Before an item is used or placed in service, procurement, inspection, and test requirements are to be satisfied.

7.2.9 The procurement system shall include provisions for inspections. Requirements for inspections shall be obtained from design documents. Inspections shall be adequate to ensure conformance with purchase requirements including verifying that specified documentation has been provided by the supplier. The

inspections shall verify that items were not damaged during shipment.

Inspection may include the following methods:

- inspections of materials or equipment at the suppliers's plant;
- receipt inspection of the shipped items;
- review of objective evidence such as certifications and reports and;
- verification of testing of items prior to or following shipment.

7.2.10 The actual performance of items is to be compared with original performance criteria. User group surveys, supplier evaluations, inspection and test results, and performance data are to be reviewed to determine procurement effectiveness.

7.2.11 The quality of purchased items and services is to be verified at intervals and to a level consistent with the complexity, risk, quantity, and procurement frequency of the items or services. A graded approach, as specified in Appendix D - Graded Approach for Quality Levels, shall be used to ensure that the resources applied are commensurate with the importance of the result to the achievement of site goals.

7.2.12 Verifications are to be executed in all phases of procurement. This may require verification of suppliers below the first tier.

7.2.13 The nonconformance and corrective action process shall address a formalized process to document occurrences when purchased items or services do not meet specifications.

7.2.14 In cases where there are indications that suppliers knowingly supplied items or services of substandard quality, FDF shall report the information to the DOE Office of Inspector General.

7.2.15 Supplier generated documents shall be accepted through the procurement system and controlled and processed by the end-user organization according to the provisions of Criterion 4 (Document and Records).

These documents may include certificates of conformance, drawings, analyses, test reports, maintenance, data, nonconformances, corrective actions, approved changes, waivers, and deviations.

7.3 RESPONSIBILITIES

7.3.1 Contracts and Asset Management Organization shall establish and implement a management system to ensure that the procurement process is documented and controlled and that procured items and services conform to established specifications.

This process shall provide for the following, as appropriate: procurement source evaluation and selection, evaluation of objective evidence of quality furnished by the supplier, source inspections, supplier audits, and examination of deliverables.

7.3.2 FDF Requisitioners shall identify, control, and implement procurement activities to ensure adequate quality (including listing the quality level in procurement documents) and to ensure that procured items and services conform to established specifications.

7.3.3 Contractors and Suppliers shall meet quality requirements for work performed or for items and services provided by their subcontractors and suppliers.

7.3.4 Quality Assurance Organization shall:

- Review procurement documents for incorporation of quality assurance requirements.
- Evaluate potential supplier's QA Program, procedure documents, and QA record submittals for concurrence with quality requirements.
- Participate with Procurement in supplier evaluations.
- Verify that purchased items and services meet procurement requirements (e.g., receipt inspection).
- Perform source inspections and reviews.
- Perform supplier/vendor/subcontractor audits.
- Perform supplier/vendor/subcontractor surveillances

8.0 CRITERION 8 - INSPECTION AND ACCEPTANCE TESTING

8.1 SCOPE

This criterion describes requirements and responsibilities for performing inspection and acceptance testing. Inspection and acceptance testing of specified items and processes shall use established acceptance and performance criteria and require calibration and maintenance of equipment used for inspections and tests.

Inspections and acceptance tests shall be conducted according to a graded approach. Results of these activities shall be documented and retained as project records.

8.2 INSPECTION REQUIREMENTS

8.2.1 A program shall be established and implemented to specify when and what type of inspections (e.g., source, in-process, final receipt, maintenance, and in-service) are required.

Administrative controls and status indicators are to be used to preclude inadvertent bypassing of required inspections and to prevent inadvertent operation of the item.

8.2.2 The level of inspection and degree of independence of inspection personnel shall be based on risk and complexity. Inspections and tests shall be conducted according to a graded approach.

8.2.3 Provisions shall be established to ensure that inspection planning is properly accomplished. Planning activities are to identify item characteristics and processes to be inspected, the inspection techniques, the acceptance criteria, and the organization responsible for performing the inspection.

Systems, Structures, and Components requiring inspection/test are to be identified early in the design phase. Acceptance parameters and other requirements such as inspection/test equipment or qualified inspection/test personnel shall be specified in design documents.

The types of Systems, Structures, and Components and the length of time they are to remain in storage shall be considered when generating the inspection or test plan.

8.2.4 When appropriate, inspection hold points shall be defined beyond which work is not to proceed until inspection has been completed.

8.2.5 When acceptance criteria are not met, nonconformances are to be documented, resolved, and corrected areas are to be reinspected.

8.2.6 Inspection/test documentation shall contain provisions for the following as applicable:

- identification of characteristics to be examined;
- required qualifications of individuals who perform the examination;
- a description of the examination methods including equipment and calibration requirements;
- acceptance and rejection criteria;
- suitable environmental conditions;
- required safety measures; and
- mandatory hold points, when required.

8.2.7 Inspection/test results shall be evaluated and verified by authorized personnel to document that all requirements have been satisfied.

8.2.8 Records shall identify the following as applicable:

- item tested;
- date of test;
- tester or data tester;
- observations;
- results and acceptability; and
- action taken concerning any nonconformances noted.

8.3 ACCEPTANCE TESTING REQUIREMENTS

8.3.1 A test control program shall be established as required and implemented for acceptance testing to demonstrate that items will perform as intended. The test control program is to include, as appropriate, bench tests and proof tests before installation, pre-operational tests, post-maintenance tests, post-modification tests, and operational tests all based on a graded approach.

8.3.2 The testing program may be implemented by or for the organization performing the work to be tested. When an organization who installed the work performs its own testing, personnel within that organization are not to test their own work for acceptance unless a third-party verification from a qualified third party is obtained, where applicable.

8.3.4 The criteria that specifies when testing is required shall be defined. Administrative controls and status indicators, such as tags and labels, are to be used to preclude inadvertent bypassing of required tests and to prevent inadvertent operation of the item.

8.3.5 Organizations shall ensure that test procedures are developed and include instructions and prerequisites to perform the test, test article configuration, use of test equipment, acceptance criteria, inspection hold points as required, and provisions of recording test data and its review for completeness and accuracy of the results.

8.3.6 When acceptance criteria are not met, corrected areas are to be retested, after being corrected, to original requirements.

8.4 ENVIRONMENTAL TESTING REQUIREMENTS

8.4.1 Chemical, Radiochemical, Geotechnical, and Asbestos analyses and tests in support of environmental studies shall meet the requirements specified in the *SCQ* (as approved by DOE and EPA).

8.4.2 Data collected for environmental projects shall be validated at the appropriate Analytical Support Level (ASL) in accordance with the requirements of the *SCQ* (as approved by DOE and EPA) prior to use.

8.5 MEASURING AND TEST EQUIPMENT REQUIREMENTS

8.5.1 A program shall be established and implemented to control the calibration, maintenance, accountability, and use of equipment used for acceptance of items during inspection and testing.

8.5.2 The types of equipment covered by the program (such as instruments, tools, gages, reference and transfer standards, and nondestructive examination equipment) are to be defined.

8.5.3 Measuring and test equipment is to be calibrated at specified intervals (or immediately before or after use) on the basis of the item's required accuracy, intended use, frequency of use, stability characteristics, and other conditions affecting its performance.

When applicable, measuring and test equipment shall be calibrated to standards traceable to the National Institute of Standards and Technology (NIST).

8.5.4 Measuring and test equipment is to be labeled, tagged, or otherwise controlled to indicate its calibration status and ensure traceability to calibration data.

Documentation showing traceability to standards shall be maintained for each piece of measuring and test equipment.

8.5.5 Measuring and test equipment is to be calibrated against standards having an accuracy that will ensure that the equipment being calibrated will be within required tolerances. If nationally recognized standards exist, calibration standards are to be traceable to them. Except where calibration standards with the same accuracy as the instruments being calibrated are shown to be adequate for the requirements, calibration standards are to have a greater accuracy than the standards being calibrated.

8.5.6 Measuring and test equipment found out of calibration shall be tagged or segregated and not used until it is recalibrated. The acceptability of items measured, inspected, or tested with an out of calibration device is to be determined.

8.6 RESPONSIBILITIES

8.6.1 Leadership of applicable FDF Organizations:

- Establish and implement procedures or identify standards for inspections and acceptance testing of engineered systems, components, or parts according to the design specifications and planning requirements.

- Establish and implement procedures to ensure that measuring and test equipment is of the proper type, range, and accuracy, and is properly calibrated, maintained, and used according to design specifications.

- Identify measuring and test equipment which require calibration. Identify applicable standards for the calibration requirements. Documentation showing traceability to standards shall be maintained for each piece of measuring and test equipment.

- Establish chemical analysis controls for the test and examination services provided to support site restoration, environmental monitoring, and health programs.
- Ensure personnel perform the test, record data, and implement corrective action for nonconforming conditions.
- Prevent inadvertent use of nonconforming materials.

8.6.2 FDF personnel shall:

- Check items supplied to their work process to ascertain that items are correct and suitable for use.
- Implement procedures for inspection and acceptance activities to ensure that items and services meet established requirements
- Ensure that measuring and test equipment used is calibrated, maintained, and conforms to established specifications.

8.6.3 The Quality Assurance Organization shall:

- Review and approve test procedures.
- Prepare and issue inspection plans.
- Perform in-process and final inspections.
- Verify tests.
- Review inspection plans for construction, restoration, waste handling, and site supporting activities as part of independent overview activities.
- Provide independent verification of compliance to test requirements.
- Ensure nonconformances are resolved.

8.6.4 Project organizations shall prepare test procedures, designate test acceptance criteria, monitor test performance, and evaluate test results.

FUNCTIONAL CATEGORY C: ASSESSMENT

The Assessment Category provides for periodic assessment of the QA Program to determine its effectiveness and to promote quality improvement. This category:

- Describes the organizational freedom and authority of the QA organization.
- Includes provisions for the qualification of persons conducting assessments.
- Provides for the auditing of operations, systematic handling of nonconforming conditions, and learning through corrective actions, trending, and root cause analyses.

The Assessment Category is composed of the following criteria:

- Criterion 9 - Management Assessment
- Criterion 10 - Independent Assessment

9.0 CRITERION 9 - MANAGEMENT ASSESSMENT

9.1 SCOPE

This criterion describes the requirements and responsibilities for regularly assessing and documenting the adequacy and effectiveness of the QA program in providing the framework for FDF's achieving its mission and objectives.

All levels of FDF leadership are required to periodically assess the integrated QA Program and its performance, and to identify and correct problems that hinder the organization from achieving its quality objectives.

These management assessments should focus on whether the integrated QA management system is accomplishing the goal of continuous improvement of the safety and reliability of products and services to effectively meet the expectations of external and internal customers.

9.2 REQUIREMENTS

9.2.1 A program of planned and periodic management assessments shall be established and implemented. Implementation of the program is to focus on how well the integrated QA Program is working by identifying barriers which hinder the organization from achieving its objectives in accordance with quality, safety, and environmental requirements.

9.2.2 Management assessments shall be conducted in accordance with a plan, and should focus on management elements that affect work processes, such as strategic planning, organizational interfaces, cost control, use of performance indicators, staff training and qualifications, and supervisory oversight and support.

Effective management assessments should also assess such areas as the state of employee knowledge, motivation, and morale; the amount of mutual trust and communication among workers; the existence of an atmosphere of creativity and improvement; and the adequacy of human and material resources.

Direct observation of work is a particularly effective method of management assessment, because it places the assessor in the position to become aware of all interactions at a work location.

Other methods of assessment, which are most effective when combined with work observation, include interviews of personnel, reviews of documentation, and conduct of drill or exercises.

9.2.3 Implementation of the Management Assessment Program may be delegated in part, but FDF leadership is to retain overall responsibility for the program. Direct participation by FDF leadership is essential, but the process should involve FDF senior leadership as well.

9.2.4 Management assessment results are to be documented. Management/leadership is to take prompt action and document resulting decisions in response to recommendations which result from the management assessment process. Follow-up is to include an evaluation of the effectiveness of recommended actions.

9.3 RESPONSIBILITIES

9.3.1 FDF Leadership shall:

- Conduct annual assessments of performance based on compliance and performance data from internal evaluations and independent assessments.
- Take prompt action and document resulting decisions in response to recommendations which result from the management assessment process.

9.3.2 FDF's Executive Program Leads shall:

- Conduct an overall assessment of FDF performance using results from the individual organization assessment activities.
- Monitor and guide those organizations responsible for corrective action.

9.3.3 FDF's Employee Advocate shall provide the FDF President and/or other appropriate FDF leadership representatives with direct information from FDF personnel and with trend analysis to augment the other management assessment methods.

10.0 CRITERION 10 - INDEPENDENT ASSESSMENT

10.1 SCOPE

This criterion describes the requirements and responsibilities for the implementation of an independent assessment program. The FDF independent assessment program evaluates the adequacy and effectiveness of activities for compliance with applicable requirements.

The independent assessment process should use a performance-based approach with emphasis on results and with compliance viewed as the baseline. Assessments should be conducted on activities that most directly relate to final objectives and should emphasize safety, reliability, and product performance. Independent assessments may include such methods as inspections, peer and technical reviews, audits, surveillances, or combinations thereof.

10.2 REQUIREMENTS

10.2.1 A program for the planning and performance of independent assessments shall be established and implemented. The FDF Oversight and Program Integration Organization shall be primarily responsible for sitewide independent assessments.

As such, the Oversight and Program Integration Organization Program Leader reports directly to the President of FDF, and has no responsibilities regarding the achievement of FDF objectives which would affect the Oversight and Program Integration leadership or the organization's independence.

Implementation shall focus on improving items and processes by emphasizing line organization's achievement of quality in compliance to environmental, safety, and health requirements.

10.2.2 Personnel performing independent assessments are to monitor work performance, identify non-compliance activities and other abnormal performance and precursors of potential problems, identify opportunities for improvement, document and report results to a level of FDF leadership having the authority to effect corrective action, and verify satisfactory resolution of problems.

10.2.3 Personnel performing independent assessments shall have the necessary technical knowledge to accurately observe and evaluate activities being assessed and to focus on improving the quality of the processes that lead to achieving compliance to environmental, safety and health, and remediation requirements.

10.2.4 Personnel performing independent assessment are not to have direct responsibilities in the area they are assessing.

10.2.5 Independent assessments shall be conducted using criteria that address environmental, safety and health, and remediation requirements. The assessments shall also describe acceptable work performance and promote improvement. They shall include an evaluation to determine whether technical requirements, not just procedural compliance, are being met.

10.2.6 Scheduling of assessments and allocation of resources shall be based on status, risk, and complexity of the item or process being assessed. Scheduling shall be flexible and additional attention shall be given to areas of questionable performance.

10.2.7 Assessment results (including identified nonconformances) shall be tracked for resolution. These assessment results shall be evaluated to determine whether similar nonconformances exist elsewhere.

10.2.8 Assessment findings shall be resolved by FDF leadership having responsibility in the area assessed.

10.2.9 Follow-up reviews of nonconforming areas shall be conducted to verify corrective actions have been implemented and shall validate the corrective actions by measuring their effectiveness.

10.2.10 FDF leadership shall respond to assessments and include the following, as applicable: action to correct the nonconformance; root cause identification; actions taken to prevent recurrence; lessons learned; and actions to be taken for improvement.

10.3 RESPONSIBILITIES

10.3.1 The Quality Assurance Organization shall:

- Perform an overview of quality inspection activities.
- Document and provide activity reports to line and staff leadership.
- Identify promptly and address, as soon as practical, conditions needing corrective actions.

10.3.2 The Quality Assurance Organization shall:

- Establish and implement independent assessments that include surveillances, appraisals, reviews, and audits.
- Document and provide activity reports to line and staff leadership.
- Identify promptly and address, as soon as practical, conditions needing corrective actions.
- Perform follow-up actions to verify implementation and effectiveness of response actions.

10.3.3 Other FDF Organizations shall:

- Grant access to records, facilities, and work areas for all FDF Independent Assessment auditors and surveillance personnel, as well as DOE and EPA assessors.
- Establish and implement independent assessments, when required, that include inspections, surveillances, tests, and reviews.
- Document and report, when performed, independent assessment results to line leadership.
- Identify promptly and address as soon as practical conditions needing corrective actions.
- Perform follow-up actions to verify implementation and effectiveness of the response action (including prevention of recurrence).
- Track identified action items for resolution and evaluate to determine whether similar nonconformances exist elsewhere.

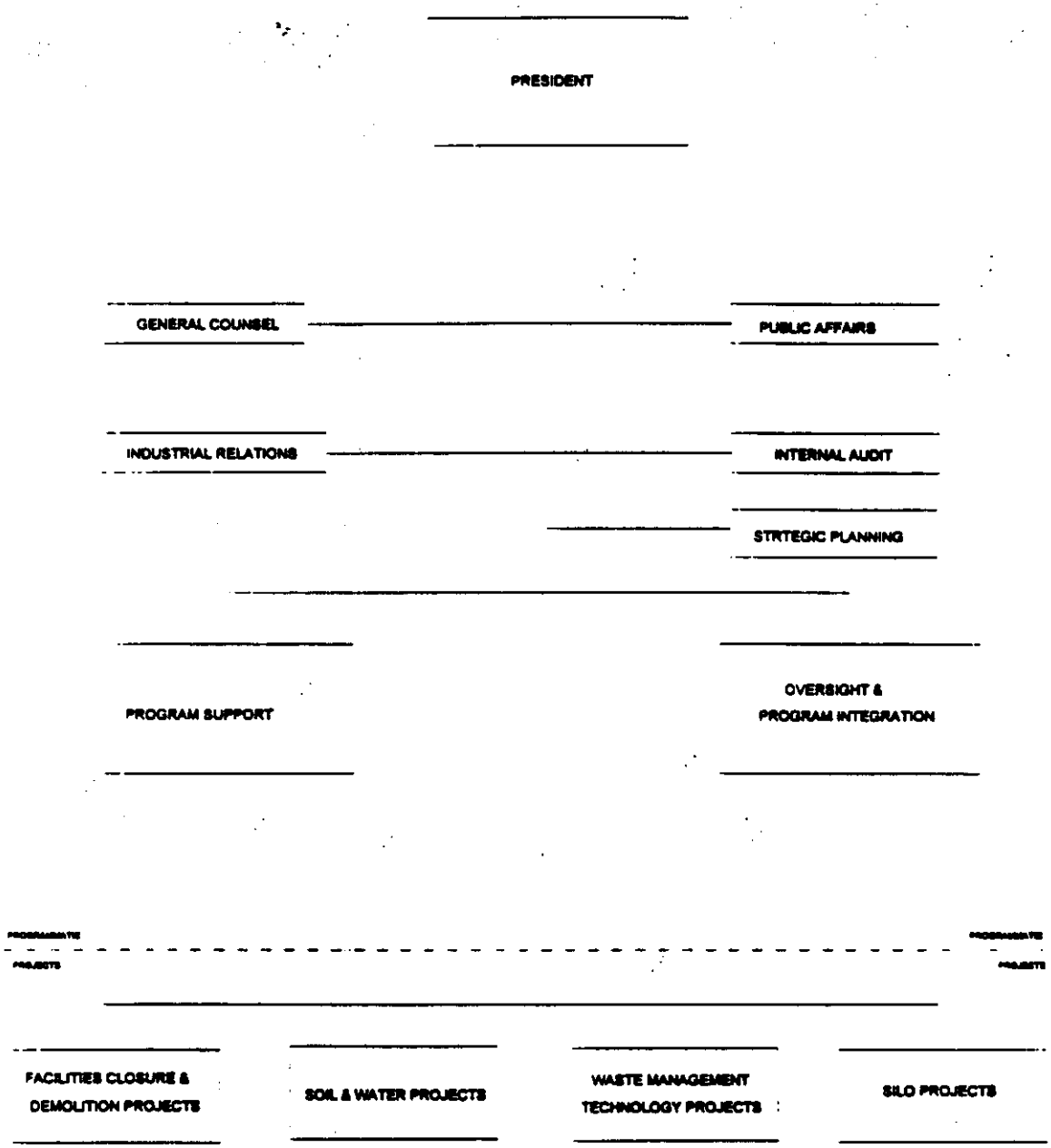
10.3.4 FDF Leadership shall:

- Identify and determine the root cause and extent of significant conditions adverse to quality.
- Provide the response to identified nonconformances.
- Take action to prevent recurrence.

10.3.5 Personnel performing assessments should focus on improving output quality and process effectiveness by emphasizing continuous improvement requirements. Assessment personnel should not reinterpret or redefine the requirements specified in approved programs. The assessors' responsibilities include:

- evaluating work performance and process effectiveness;
- identifying abnormal performance and potential problems;
- finding opportunities for improvements;
- documenting and reporting results; and
- verifying satisfactory resolutions of reported problems.

FDF ORGANIZATION CHART*



*These positions are updated and described in more detail in RM-0016, Management Plan - FDF Policies and Requirements Manual, which take precedence over the summaries given here.

FDF ORGANIZATIONS AND FUNCTIONS*

PRESIDENT	• Sets QA Policy • Authorizes Implementing Procedures
GENERAL COUNSEL	• Legal Advice • Legal Defense • Provide Guidance on Requirements and Interpretation of Environmental, Procurement, Labor and Employment Laws • Patent and Proprietary Rights with Respect to Technology Development
PUBLIC AFFAIRS	• Public Affairs • Employee Communication • Public Information/News Media Interface
INDUSTRIAL RELATIONS	• Participates in the collective bargaining process • Labor harmony • Represents FDF in all labor management processes • Employee Relations
INTERNAL AUDIT	• Operational and Financial Audits
STRATEGIC PLANNING	• Remedial priority development • Strategic interface with regulatory community • Supports technical liaison with stakeholder groups
OVERSIGHT AND PROGRAM INTEGRATION	• Quality Assurance • Programmatic Cost & Budget • Program Services • Safety & Health • Project Controls • Emergency Services • Program Planning & Integration • Environmental Compliance • Operations Assurance • Training

*This chart is provided to illustrate primary functions of FDF organizations. They are updated and described in more detail in RM-0016, Management Plan, which takes precedence over the summaries given here.

FDF ORGANIZATIONS AND FUNCTIONS

PROGRAM SUPPORT	• Human Resources • Finance • Contracts & Asset Management • Records Management • Administration Services • Information Management • Total Quality Management • Space Management • Program Services
FACILITIES CLOSURE & DEMOLITION PROJECTS	• Project Support & Integration • Enhance Work Planning • Utilities Projects • Technical Services • Facilities Shutdown Projects • Site Project Support • Facilities Demolition Projects • Maintenance • Rigging & Tool Services • Facilities Services • Supplemental Environmental Projects
SOIL & WATER PROJECTS	• Project Support & Integration • Environmental Monitoring • S&W Construction • Aquifer Restoration • Analytical Laboratory Services • Waste Pits Remedial Action • Sample & Data Management • Soil Characterization & Evacuation • On-Site Disposal Facility
WASTE MANAGEMENT & TECHNOLOGY PROJECTS	• OPS Support • LL Waste • Mixed Waste • Waste Storage & Shipment • Waste Characterization • Waste Plan & Integration • Waste Acceptance • Traffic Management • Waste Minim. & Pollution
SILO PROJECTS	• Silos 1, 2, & 3

ABBREVIATIONS, ACRONYMS, AND DEFINITIONS

10 CFR PART 830.120 - Code of Federal Regulations "Quality Assurance"

Accuracy - The closeness of a measured value to the accepted true value.

Administrative Controls - Provisions relating to organization and management procedures, record keeping, assessment, and reporting necessary to ensure safe operation of a facility. (10 CFR 830).

Amended Consent Agreement - The modified Consent Agreement signed in September 1991 which includes the renegotiation framework and schedules for developing, implementing, and monitoring appropriate response actions at the FEMP and to facilitate cooperation, exchange of information and participation of the U.S. EPA and the U.S. DOE in such actions.

ANSI - American National Standards Institute

Appraisal - A documented objective and independent evaluation of Safety & Health activities within a functional area done according to written guidance and criteria to verify that applicable elements of the performing organization's program are significant, are adhered to, and add value to the overall process according to specific departmental requirements and needs. Other criteria affecting the evaluation of an appraised activity include the adequacy, implementation, and efficiency of the activity.

Appraisals differ from audits in that they are limited to Safety & Health activities and the documented evaluation addresses additional topics to verify that applicable elements of the performing organization's program are significant and add value to the overall process according to specific departmental requirements and needs and also the efficiency of the activity.

ASME - American Society of Mechanical Engineers

ASNT - American Society for Nondestructive Testing

Assessment/Verification - The act of reviewing, inspecting, testing, checking, conducting surveillances, auditing, or otherwise determining and documenting whether items, processes, or services meet specified requirements. The terms assessment and verification are synonymous; their use is determined by who is performing the work. Assessments are performed by or for senior management. Verifications are performed by the line organization.

Audit - A planned and documented activity systematically performed to determine by investigation, examination, or evaluation of objective evidence the quality of operation of some function or activity. Audits may be of two basic types: (1) performance audits in which quantitative data are independently obtained for comparison with routinely obtained data in a measurement system, or (2) system audits of a qualitative nature that consists of an on-site review of the quality assurance system and physical facilities for sampling, calibration, and measurement.

External Audit (Audit by an Outside Organization) - A formal examination (of FEMP activities) planned and conducted by an organization other than the FEMP, such as DOE. This includes their Technical Safety Appraisals (TSA), Management Appraisals, and Functional Appraisals.

Internal Audit - The Internal Audit organization provides an independent audit function at the Fernald Environmental Management Project (FEMP). Internal Audit is responsible for serving FDF and DOE management through periodic examination and evaluation of various activities at FEMP, including the adequacy and effectiveness of internal control systems; the quality and efficiency of performance; the allowability of costs; and compliance with DOE directives, regulations, and guidelines. Internal Audit's function is to perform timely, quality audits that examine the financial and operational nature of FDF activities.

Internal Independent Audit - A formal examination and evaluation of a FDF organization's activities by the FDF Independent Assessment (IA) Organization to determine the status and assess the adequacy and effectiveness of the implementation of FDF procedures and compliance to requirements.

Supplier Audit - An audit of the QA Program activities of suppliers of materials and services to the FEMP. Included within this definition are the contractor(s) performing remediation and/or restoration services and the contractor(s) performing architect/engineer services.

CFR - Code of Federal Regulations

Chain-of-Custody Procedure - A procedural sequence of events which tracks sample custody or possession. A sample is considered in custody if it is in an authorized person's possession; locked so that no one can tamper with it; after having been in physical custody; and/or in a secured area, restricted to authorized personnel.

Charter - A document approved by the FDF President defining the work scope and responsibilities of a particular department or committee.

Comparability - A measure which expresses the confidence with which one data set can be compared to another. Comparability for a program is achieved by ensuring that all sampling and analysis use specified uniform procedures.

Completeness - A measure of the amount of valid data obtained from a measurement system compared to the amount that was expected to be obtained under normal conditions.

Compliance - Adherence to mandatory regulatory orders and directives.

Compliance Activity - A specific activity identified during the review of the QA Rule and Safety Guide which is required to implement a particular section or requirement of the QA Rule.

Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) - An act enabling the EPA to investigate and clean up abandoned or uncontrolled hazardous waste sites.

Computer Program - A sequence of instructions suitable for processing by a computer. Processing may include the use of an assembler, a compiler, an interpreter, or a translator to prepare the program for execution as well as to execute it. Computer programs impacted by the FDF QA Program are those used for design analysis, process or operations control, or data base or document control registers when used as the controlled source of quality information.

Condition Adverse to Quality - An all-inclusive term used in reference to any of the following failures, malfunctions, deficiencies, defective items, and nonconformance. A significant condition adverse to quality is one which, if uncorrected, could have a serious effect on safety or operability.

Consent Agreement (CA) - The Consent Agreement is an agreement between the U.S. EPA and DOE: (1) To ensure the environmental impacts associated with the past and present activities at FEMP are thoroughly investigated and appropriate response actions(s) taken are necessary to protect the public health, welfare, and the environment. (2) To establish a procedural framework and schedule for developing, implementing, and monitoring appropriate response action at FEMP in accordance with CERCLA, the National Contingency Plan, and EPA Superfund guidance and policy; and (3) To facilitate cooperation, exchange of information and participation between the parties involved.

Contractor - Any person under contract with the Department of Energy with responsibility to perform activities in connection with a nuclear facility (10 CFR 830).

Controlled Document - Any document for which distribution and status are to be kept current by the issuer in order to ensure that authorized holders or users of the document have available the most up-to-date version for accomplishment of work action.

Corrective Action - Measures taken to rectify significant conditions adverse to quality and, where necessary, to preclude repetition.

Data Quality - The totality of features and characteristics of data that bears on the data's ability to satisfy a stated purpose. The characteristics of major importance are accuracy, precision, completeness, representativeness, comparability, traceability, and authenticity.

Deviation - A departure from specified requirements.

Document - Any written or pictorial information describing, defining, specifying, reporting, or certifying activities, requirements, procedures, or results. A document is not considered to be a Quality Assurance Record until it satisfies the definition of a Quality Assurance Record as defined in this Appendix.

DOE - U.S. Department of Energy

DOE 5400.1 - DOE Order entitled "General Environmental Protection Program"

DOE 5700.6C - DOE Order entitled "Quality Assurance"

Environmental Compliance - Adherence to those requirements established by DOE Orders and Federal and State Regulatory Agencies that address environmental protection of the FEMP and environs.

Environmentally Related Measurements - A term used to describe essentially all field and laboratory measurement of chemical, physical, or biological parameters in the environment; determining the presence or absence of priority pollutants in waste streams; health and ecological effect studies; clinical and epidemiological investigations; engineering and process evaluations; studies involving laboratory simulation of environmental events; and studies or measurements of pollutant transport, including diffusion models.

EPA - U.S. Environmental Protection Agency

FEMP - Fernald Environmental Management Project

FDF - Fluor-Daniel Fernald

FMPC - Feed Materials Production Center (now the FEMP)

Graded Approach - a process by which the level of analysis, documentation, and actions necessary to comply with a requirement in this part are commensurate with:

(1) The relative importance to safety, safeguards, and security;
(2) The magnitude of any hazard involved;
(3) The life cycle stage of a facility;
(4) The programmatic mission of a facility;
(5) The particular characteristics of a facility; and
(6) Any other relevant factor (10 CFR 830).

Hazard - A source of danger (i.e., material, energy source, or operation) with the potential to cause illness, injury, or death to personnel or damage to a facility or to the environment (without regard for the likelihood or credibility of accident scenarios or consequence mitigation). (10 CFR 830)

Implementation Plan - A document prepared by a contractor that sets forth:

(1) When and how the actions appropriate to comply with the requirements of a section of 10 CFR Part 830, including the requirements of a plan or program required by the section, shall be taken, and

(2) What relief will be sought if a contractor cannot attain full compliance with a requirement in a reasonable manner (10 CFR 830).

Industrial Facility - A facility in which the hazards are limited to Standard Industrial Hazards.

Inspection - Examination or measurement to verify whether an item or activity conforms to specified requirements.

Item - An all-inclusive term used in place of any of the following: appurtenance, facility, sample, assembly, component, equipment, material, module, part, structure, subassembly, subsystem, system, unit, or support systems.

Measuring and Test Equipment (M&TE) - Devices or systems used to calibrate, measure, gage, test, or inspect in order to control or acquire data to verify conformance to specified requirements.

Nonconformance - A deficiency in characteristic, documentation, or procedure that renders the quality of an item or activity unacceptable or indeterminate.

Nonconforming Condition - An item or process which does not comply with specified requirements in one or more characteristics.

Non-Reactor Nuclear Facility - Those activities or operations that involve radioactive and/or fissionable materials in such form and quantity that a nuclear hazard potentially exists to the employees or the general public. Included are activities or operations that -

(1) Produce, process, or store radioactive liquid or solid waste, fissionable materials, or tritium;
(2) Conduct separations operations;
(3) Conduct irradiated materials inspection, fuel fabrication, decontamination, or recovery operations;
(4) Conduct fuel enrichment operations; or
(5) Perform environmental remediation or waste management activities involving radioactive materials.

Incidental use and generating of radioactive materials in a facility operation (e.g., check and calibration sources, use of radioactive sources in research and experimental and analytical laboratory activities, electron microscopes, and X-ray machines) would not ordinarily require the facility to be included in this definition (10 CFR 830).

Nuclear facility - Reactor and nonreactor nuclear facilities (10 CFR 830).

Ohio EPA - Ohio Environmental Protection Agency

Person - Any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, Government agency, any State or political subdivision of, or any political entity and any legal successor, representative, agent or agency of the foregoing: provided that person does not include the Department of Energy or the United States NRC (10 CFR 830).

Precision - A measure of mutual agreement among individual measurements of the same property, usually under prescribed similar conditions. Precision is best expressed in terms of the standard deviation. Various measures of precision exist depending upon the "prescribed similar conditions". The precision of an analytical method is determined from the results of duplicate samples.

Preventive Maintenance - Maintenance performed for precautionary reasons to protect against malfunction or failure.

Procedure - A document that specifies or describes how an activity is to be performed.

Process - A series of actions that achieve an end or result (10 CFR 830).

Procurement Document - Purchase requisitions, purchase orders, drawings, contracts, specifications, or instructions used to define requirements for purchase.

Product - Any item (hardware, software, service, document) produced for a customer.

PSO - Program Secretarial Officer; a head of a DOE office with responsibility for one or more specific facilities.

QAMS - Quality Assurance Management Staff; an EPA organization.

Quality - The condition achieved when an item, service, or process meets or exceeds the user's requirements and expectations (10 CFR 830).

Quality Assurance (QA) - All those actions that provide confidence that quality is achieved (10 CFR 830).

Quality Assurance Program (QAP) - The overall program established by FDF to implement the quality assurance requirements imposed on the FEMP by its customers. The Program assigns responsibilities and authorities, defines policies and requirements, and provides for the performance and assessment of work (10 CFR 830).

Quality Assurance Project Plan (QAPjP) - An orderly assembly of detailed and specific procedures by which an agency delineates how it produces quality data for a specific project or measurement method. A given agency would have only one quality assurance program plan, but would have a quality assurance plan for each of its projects or programs (group of projects using the same measurement methods; for example, a laboratory service group might develop a plan by analytical instrument since the service is provided to a number of projects).

Quality Assurance Record - A completed document that furnishes evidence of the quality of items and/or activities affecting quality. Records verifying compliance with regulatory requirements are quality assurance records. THESE RECORDS ARE OFTEN GENERATED BY ORGANIZATIONS OTHER THAN THE OVERSIGHT AND PROGRAM INTEGRATION ORGANIZATION.

QA Rule - Term used to describe the requirements in 10 CFR 830.120, "Quality Assurance Requirements."

Quality Control (QC) - The overall system of technical activities that measures and controls the quality of a process, item, or service so that it meets the stated needs of the user.

Quality Level - The level of analysis, documentation, and other actions necessary to implement the QA program requirements based on the Graded Approach. There are four Quality Levels established at the FEMP, QL-1, QL-2, QL-3 and QL-4. Quality Level 3 establishes the basic Quality Management System that implements the QA Program requirements of 10 CFR 830.120. QL-1 and QL-2 apply additional resources and vigor required to control the increasingly higher risk and/or hazards. Quality Level 4 represents the appropriate level of resources applied to the purchase of non-safety related items.

Record - A completed document or other media that provides objective evidence of an item, service, or process (10 CFR 830).

Resource Conservation and Recovery Act (RCRA) - An act which enabled the EPA to issue regulations for a national hazardous waste management program. The regulations govern hazardous waste from the time it is created to the time of its disposal. Any waste that is transported off the site for treatment, storage, or disposal must be accompanied by a manifest that: (a) Identifies who generated the waste, (2) Provides a full description of the contents and quantity of the waste, and (3) Designates the facility to which it must be shipped.

Representativeness - Expresses the degree to which data accurately and precisely represent a characteristic of a population, parameter variations at a sampling point, process condition, or an environmental condition. Data representativeness is a function of sampling strategy; therefore, the sampling scheme should be designed to maximize representativeness.

Restoration - The environmental rejuvenation of the site and its surroundings to a former state or condition which (1) does not present a threat or hazard to the public health and welfare and the environment or (2) which effectively mitigates and minimizes the threat or hazard to the public health and welfare and the environment.

Risk - A quantitative or qualitative expression of possible loss in terms of consequence severity and probability of occurrence.

Service - The performance of work, such as design, construction, fabrication, inspection, nondestructive examination/testing, environmental qualification, equipment qualification, repair, installation, or the like. (10 CFR 830)

Sitewide CERCLA Quality Assurance Project Plan (SCQ) - This document, as approved by DOE and EPA, provides overall sitewide quality assurance planning for environmental sampling and analysis at the FEMP.

Standard Operating Procedure (SOP) - An operation, analysis, or action whose mechanics are thoroughly prescribed and documented and which is commonly accepted as the usual or normal method for performing certain routine or repetitive tasks.

Supplier - Any individual or organization who furnishes items or services in accordance with a procurement document. An all-inclusive term used in place of any of the following: vendor, seller, contractor, subcontractor, fabricator, consultant, and their subtier levels.
Surveillance - The act of monitoring or observing to verify whether an item or activity conforms to be specified requirements.

Validation - The process of evaluating a product at the end of the entire development process to ensure compliance with requirements, or the measurement of effectiveness regarding corrective actions.

Work - Process of performing a defined task or activity; for example, research and development, operations, maintenance and repair, administration, software development and use, inspection, safeguards and security, data collection, and analysis.

GRADED APPROACH FOR QUALITY LEVELS

1.0 GRADED APPROACH

The QA Rule is applicable to the entire FEMP site through the use of a Graded Approach. The requirements of 10 CFR 830.120 will be graded and used for all site programs, including those which have little or no nuclear safety significance.

In order to ensure the most efficient use of resources, a graded approach is used to determine the rigor with which the QA management system is applied to a specific facility or activity. This approach provides the flexibility to implement the program in a way that best suits the facility or activity while maintaining full compliance with the QA Rule.

A graded approach is the process by which the levels of analysis, documentation, and other actions necessary to implement the QA Program requirements are based on facility/activit- specific factors.

The scope and depth of the management system's application of requirements to a specific activity should be determined by the use of a grading process. The grading process provides the flexibility to design controls that best suit the facility or activity. The graded approach process should determine the appropriate level of effort necessary to attain and document the requirements established through the consideration of prescribed factors. This process is based on prescribed facility-specific or activity-specific factors such as the:

- level of risk;
- age, status, and condition of a facility or process;
- history of problems at a site or facility;
- adequacy of existing safety documentation; and
- complexity of products or services involved.

The graded approach and the establishment of Quality Levels are used to determine the appropriate level of effort necessary to implement the requirements of 10 CFR 830.120 and are not used to obtain relief from the requirements.

Quality Levels have been established based on categorization rules which are applicable at two levels: 1) entire Facilities/Activities and 2) Structures, Systems or Components (SSC) in the facility or used in the activity. This process is documented in Attachment D1, "Categorization Criteria for Facilities/Activities and Systems, Structures, and Components" which was used to develop the Quality Level Matrix shown in Tables 1, 2, and 3.

Since Quality Level 3 is the basic Quality Management System that implements the QA Program requirements of 10 CFR Part 830.120, all support organizations and functional areas will operate under a Quality Level 3 program. If these organizations are involved in a specific activity or task which is deemed to be at a higher Quality Level (1 or 2), then they will apply the appropriate resources required by that Quality Level.

Quality Level 4 is not intended to implement all of the QA program requirements for site facilities or activities. At this level, an adequate amount of resources are applied as defined in project specific plans or purchase orders.

The Quality Assurance Program (*QAP*) includes specific requirements associated with the four Quality Levels. These requirements are documented in the "Application of Quality Levels to QA Program Criteria" chart, Attachment D2. Appropriate QA elements will be applied to each Facility/Activity and Structures, Systems, or Components (SSC) in accordance with the Quality Level established in the following Tables (1,2,3) and the requirements documented in Attachment D2. The activities and programs required by the *QAP* implement the provisions of the QA Rule. This information is documented further in Attachment D2 and in the following.

GRADED APPROACH FOR QUALITY LEVELS (continued)

TABLE 1

FACILITY/ACTIVITY	
NUCLEAR HAZARD CATEGORY	QUALITY LEVEL FOR WRITTEN PROGRAM
HAZARD CATEGORY 1 (HC1)	QL-1
HAZARD CATEGORY 2 (HC2)	QL-2*
HAZARD CATEGORY 3 (HC3)	QL-3*

TABLE 2

FACILITY/ACTIVITY	
NON-NUCLEAR HAZARD CATEGORY	QUALITY LEVEL FOR WRITTEN PROGRAM
HIGH HAZARD CLASS (HH)	QL-1
MODERATE HAZARD CLASS (MH)	QL-2*
LOW HAZARD CLASS (LH)	QL-3*

GRADED APPROACH FOR QUALITY LEVELS (continued)

TABLE 3

SYSTEMS, STRUCTURES, AND COMPONENTS	
PERFORMANCE GRADE CATEGORY	QUALITY LEVEL FOR SSC
PG-1	QL-1
PG-2	QL-2*
PG-3	QL-3*
PG-4	QL-4*
PG-5	QL-4*

* DURING THE PERFORMANCE GRADING PROCESS, THE TECHNICAL REVIEW TEAM MAY ESTABLISH A HIGHER QUALITY LEVEL BASED ON SPECIAL CONSIDERATIONS.

2.0 QUALITY LEVELS

The "Application of Quality Levels to QA Program Criteria" matrix charts, Attachment D2, provides both prescriptive guidance and broad based requirements for assignment of the appropriate resources necessary to implement a Quality Assurance program based on the risk, hazard, safety and cost significance of a particular facility, activity, system, structure, or component (as defined by Hazard Categories, safety systems, and Quality Levels.)

These matrix charts are provided for reference purposes and should be used by management to develop their documented program and procedures in accordance with the safety significance of their work. They should also be used to develop subcontractor requirements, procurement specifications and design requirements for all products or services purchased by FDF. In addition, the matrix charts serve as a tool for assessors of these programs to ensure that appropriate resources have been applied to the QA management system developed for that work, whether the work is performed by FDF or a subcontractor.

Quality Level - the level of analysis, documentation, and other actions necessary to implement the QA Program requirements based on the Graded Approach. There are four Quality Levels established at the FEMP: QL-1, QL-2, QL-3 and QL-4.

Quality Level 3 establishes the basic Quality Management System that implements the QA Program requirements of 10 CFR 830.120.

QL-1 and QL-2 apply additional resources and vigor required to control the increasingly higher risk and/or hazards.

Quality Level 4 represents the appropriate level of resources applied to non-safety related services or to the purchase of non-safety related items. These definitions are expanded below:

- Quality Level 1 (QL-1) - This Quality Level includes the basic Quality Management System of QL-2 plus the additional resources and vigor necessary for control and protection due to the highest risks and/or hazards at the site.

  Quality Level 1 is generally applied to facilities/activities which are categorized as Hazard Category 1 or High Hazard Class as described in Table 1 or Table 2 and Attachment D2.

  Quality Level 1 is also generally applied to Systems, Structures, and Components which are categorized as Performance Grade 1 as described in Table 3, and Attachment D2.

- Quality Level 2 (QL-2) - This Quality Level includes the basic Quality Management System of QL-3 plus the additional resources and vigor necessary for control and protection due to the higher risks and/or hazards.

  Quality Level 2 is generally applied to facilities/activities which are categorized as Hazard Category 2 or Moderate Hazard Class as described in Table 1 or Table 2 and Attachment D2.

  Quality Level 2 is also generally applied to Systems, Structures, and Components which are categorized as Performance Grade 2 as described in Table 3 and Attachment D2.

- Quality Level 3 (QL-3) - This is the basic Quality Management System that implements the QA Program requirements (10 criteria) of 10 CFR 830.120.

  Quality Level 3 is generally applied to facilities/activities which are categorized as Hazard Category 3 or Low Hazard Class as described in Table 1 or Table 2 and Attachment D2.

  Quality Level 3 is also generally applied to Systems, Structures, and Components which are categorized as Performance Grade 3 as described in Table 3 and Attachment D2.

- Quality Level 4 (QL-4) - This Quality Level is not intended to implement all of the QA program requirements for site facilities or activities. At this level, an adequate amount of resources are applied as defined in project specific plans or purchase orders.

  Applicable technical and administrative requirements (such as specifications, codes, standards, tests and inspections, and acceptance criteria) for procurement of items and services shall be clearly stated in the procurement documents.

  Quality Level 4 is generally applied to facilities or activities which are categorized as a Radiological Facility or an Industrial Facility as described in Table 1 or Table 2 and Attachment D2.

  Quality Level 4 is also generally applied to Systems, Structures, and Components which are categorized as Performance Grade 4 or 5 as described in Table 3 and Attachment D2.